REMARKS

Applicant thanks the Examiner for the interview of June 11, 2009, in which prior art references Mosse et al. and Krulevitch et al. were discussed.

The claims have been amended to further define the invention and distinguish the claims over the cited prior art. Claims 17 and 20 are drawn to methods, which now require insertion of instrument into a tissue volume using a device that has a sharp distal end and a plurality of tissue sampling devices. The sharp distal end mediates piercing and insertion into the depths of a tissue, and many sampling devices arranged along the longitudinal axis of the device obtain tissue samples from anatomical locations at varying depths within the tissue to map the variation of tissue in a given line or direction. Multiple linear samples are taken from within a tissue, e.g., in the vicinity of a diseased area, to evaluate the extent of change of tissue characteristics. In this manner, the method permits geographic cytology with minimal damage to the area to be mapped.

Amended claims 17 and 20 and new claims 31-40 are supported by Fig. 1 and by disclosure at page 7, lines 15-23; page 8, lines 8-9; and page 12, line 32, to page 13, line 4.

No new matter has been added by this amendment.

35 U.S.C. §112, second paragraph

The Examiner states, "it is unclear in light of applicants specification what is encompassed by about 50". Claims 29 and 30 have been amended to delete the word "about". Applicant therefore requests withdrawal of this ground of rejection.

35 U.S.C. §103

Claims 1-6, 8, 10, 12, 17-19, and 27-30 were rejected for obviousness over Mosse et al., (WO 00/44285) or the combination of Mosse et al. and Krulevitch et al. (U.S. Patent 5,928,161). Claims 7, 20-23, and 26 were rejected for obviousness over Mosse et al. (or Mosse/Krulevitch) in view of Sorenson (U.S. Patent No. 5,320,627).

Claims 1-16 have been canceled.

Mosse et al. describes a device and method of removing "surface tissue" by inserting a biopsy device into an existing bodily lumen, e.g., an esophagus, using a resiliently flexible guide member at the distal end of the instrument. Mosse et al. fails to describe a sharp distal end and fails to describe a method of extracting tissue samples from a depth of a bodily tissue as is now required by the amended claims. The method of Mosse et al. is limited to sampling the "mucosa and submucosa" of the esophagus and is specifically designed to avoid penetrating into the depths of a tissue or organ. Mosse et al. state "The recesses are made sufficiently shallow that

deep muscle is not drawn in" (page 6, lines 10-20 of Mosse et al. This reference neither describes nor suggests a sharp distal end used for penetrating into a depth of a bodily tissue. In fact, the reference emphasizes the merits of a flexible guide so as not to penetrate tissue and shallow recesses to sample only surface-exposed tissue of an existing luminal bodily structure, i.e., "tissue nearest the surface of the oesophagus".

Mosse additionally describes "A further longitudinal passage 18 runs through the core to enable it to be threaded on a guide wire." Guide wires are used in internal body lumens such digestive or cardiovascular lumens. The Mosse et al. reference describes the device passing through the esophagous and does not disclose the passage of the device through tissue. As is discussed above, the Mosse device has a "resiliently flexible guide member 7 to assist in guiding the head when it is inserted in the patient's body." The design is therefore not intended to pass through tissue. The Mosse specification teaches away from piercing tissue. Therefore, the amended claims are non-obvious over this prior art reference.

Krulevitch et al. describes a silicon-based microbiopsy cutting device the Krulevitch instrument cuts thin slices for microscopic examination. This device is also designed to perform a biopsy by going through an existing lumen - i.e., the vasculature. The method of Krulevitch is performed as follows:

> 1) intravascularly, to obtain samples of plaque, clot, or thrombus; 2) extravascularly, for biopsies of cancerous cells or tumors; 3) a device can be guided through the vasculature to the location of a tumor, for example, the vessel punctured, and a biopsy performed on externally accessible tissue, such as skin or bowel tissue. (col. 2, lines 37-42, of Krulevitch et al.)

Krulevitch also fails to describe a sharp distal end for insertion into a depth of a tissue, because regardless of whether the biopsy is taken "intravascularly" (e.g., plaque, clot or thombus) from the interior of a blood vessel or whether it samples a tumor adjacent to a blood vessel ("extravascularly"), the device is guided through the lumen of a blood vessel rather than inserted into the depths of a tissue. Thus, this reference fails to provide any additional disclosure is missing in Mosse et al. to support a determination of obviousness of the claims as now amended.

The claimed method now requires insertion into a depth of a bodily tissue, i.e., piercing a bodily tissue, and recites features indicated for that purpose. The specification (Figure 1) provides "The distal end 52 is a sharp or pointed end that is inserted into the subject requires removal of tissue or fluid samples." The end is sharp for the sole purpose of piercing tissue. If

not intended to pierce tissue, the end would not be sharp. In fact a sharp distal end in the context of any of the cited prior art references would be contradictory to the purpose of the prior art devices, and would be disadvantageous, because a sharp end would damage tissue and inhibit passage through a body lumen.

The Sorenson reference was cited merely for the disclosure of a heating element. This reference does not describe a sharp distal end of a device with a plurality of tissue sampling devices, nor does it describe a method utilizing such a tool to access a depth of a tissue to generate a cytological map as described and claimed.

In view of the distinctions and arguments presented above, Applicant respectfully requested withdrawal of the rejection for obviousness.

CONCLUSION

Applicant believes that the amended claims are in condition for allowance, which action is respectfully requested. Applicant reserves the right to prosecute claims which are equal to or broader in scope in this or future applications related to the above-identified patent application.

Should the Examiner have any questions concerning the enclosure submitted herewith, the Examiner is invited to telephone the undersigned agent of record at the number provided.

The Commissioner is hereby authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311 (Reference No. 26859-002).

Respectfully submitted,

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